K121149

MAY 16 2012

510(k) SUMMARY

A summary of 510(k) safety and effectiveness information
in accordance with the requirements of 21 CFR 807.92

Preparation Date: 6 April, 2012

Applicant/Sponsor:
Biomet Manufacturing Corp.
56 East Bell Drive
P.O. Box 587
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Contact Person:
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Proprietary Name: Vanguard® SSK 360 Revision Knee System – K093293

Common Name: Knee prosthesis

Classification Name(s): Knee joint patellofemorotibial, semi-constrained, cemented polymer/metal/polymer (21 CFR § 888.3560)

Product Code(s) JWH

Legally Marketed Devices To Which Substantial Equivalence Is Claimed:
Vanguard 360 Revision Knee System – K093293

Device Description: This submission describes modifications to compatible components of the Vanguard SSK 360 Revision Knee System. Specifically, the design and size offering was modified.

Intended Use: The Biomet® Splined Knee Stems V2 are intended for cemented fixation to provide additional stability to femoral or tibial knee components where needed.

Indications For Use:

Indications for Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis traumatic arthritis where one or more compartments are involved;
2. Correction of varus, valgus, or posttraumatic deformity;
3. Correction or revision of unsuccessful osteotomy, arthrodesis, or failure of previous total joint replacement procedure.

The Regenerex™ femoral augments are indicated for use with the Vanguard™ Total Knee System.

The Regenerex™ tibial augments are indicated for use with standard and offset Biomet® Tibial Trays.

Femoral components and tibial tray components with porous coatings are indicated for cemented and uncemented biological fixation application. Non-coated (Interlok™) devices and all-polyethylene patellar components are indicated for cemented application only. Regenerex™ components are intended only for uncemented biologic fixation application.

Summary of Technologies:

The Biomet® Splined Knee Stems V2 have the same technological characteristics as the predicate devices except for a slight modifications to the general design as described in this Special 510(k) notification. The changes do not affect the intended use or alter the fundamental scientific technology of the device. A risk analysis was conducted that evaluated the proposed modifications. The risk analysis concluded that the proposed modifications to the splined stems do not introduce any new risks.

Non-Clinical Testing:

Fit Analysis Performance Testing was conducted to determine the fit of the subject stems. All stems tested met the acceptance criteria of "acceptable stability". Secondary evaluation determined that the design modifications did not introduce any new risks of bone perforation or fracture.

An engineering justification evaluated the proposed modifications and demonstrated that the proposed design modifications would not affect the taper connection of the stems as compared to the predicate stems.

The modified stems are determined to be MR Conditional within the parameters of the previously tested Vanguard 360 Revision Knee System stems.

Clinical Testing:

Clinical Data was not required to demonstrate substantial equivalence to the predicate Vanguard® 360 Revision Knee System (K093293).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Biomet Manufacturing Corp.
% Mr. Gary Baker, Senior Regulatory Specialist
56 East Bell Drive
PO Box 587
Warsaw, IN 46581-0587

MAY 16 2012

Re: K121149
Trade/Device Name: Vanguard SSK 360 Revision Knee System
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee Joint patellofemorotibial, semi-constrained, cemented polymer/metal/polymer
Regulatory Class: II
Product Code: JWH
Dated: April 12, 2012
Received: April 16, 2012

Dear Mr. Baker:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121149

Device Name: Vanguard® SSK 360 Revision Knee System

Indications for Use:

1. Painful and disabled knee joint resulting from osteoarthritis, rheumatoid arthritis traumatic arthritis where one or more compartments are involved;
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Prescription Use YES	AND/OR	Over-The-Counter Use NO
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121149